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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,081	07/22/2005	Ole Simonsen	10200.204-US	1176

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EXAMINER	
DOUYON, LORNA M	

ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/543,081	SIMONSEN ET AL.	
	Examiner	Art Unit	
	Lorna M. Douyon	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24 and 26-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-24 and 26-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. This action is responsive to the amendment filed on August 28, 2009.

2. Claims 18-24, 26-40 are pending. Claim 40 is newly added.

Claim Rejections - 35 USC § 112

3. Claims 36-39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations "more than 51%, 52%, 54% or 56%" in claims 36-39 respectively, are not supported in the specification and are considered as new matter. The added limitations in the claims lack literal basis in the specification as originally filed, see *Ex parte Grasselli,* 231 USPQ 393 (Bd. App. 1983) *aff'd mem.* 738 F.2d 453 (Fed. Cir. 1984).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 18-24, 26-27, 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 4,009,076), hereinafter "Green".

Green teaches enzyme granules, particularly for detergent compositions, comprising a granule core of solid material carrying an enzyme and a solid coating of plasticized resin free of the enzyme (see abstract). The carrier material of the core will be of solid non-friable substance suitable for carrying the enzyme like inorganic salts, especially a detergency builder salt, and one example is sodium hexametaphosphate (see col. 2, lines 47-58). The solid material carrying the enzyme can be agglomerated with a cohesive organic material to form a core, and when present, it will usually provide from 2 to 50% by weight of the granule core, and the amount of enzyme will be chosen according to the activity of the enzyme concentrate available (see col. 3, lines 46-53), the remainder of the granule core will be the amount of the carrier. In Example 1, the carrier (which is granular sodium tripolyphosphate) is present in an amount of about 89% of the granule core (81/91.1 x 100 = 89%), see col. 5, lines 60-67. The preparation of the granule core can be carried out by conventional methods, for example, an enzyme powder can be mixed with the carrier and a concentrated solution of organic material sprayed on to it and the resulting mass extruded and formed into noodles (see col. 3, line 66 to col. 4, line 5), and thereafter coating the granule core in a Lodige mixer, a pan coater or a drum granulator (see col. 4, lines 6-43). Green also teaches a solid detergent composition comprising enzyme granules as described above (see col. 4, lines 44-47). In Example 8 and 9, Green teaches granule cores which are given a preliminary coating by atomizing on to them in the Lodige mixer a 6.1% solution of anhydrous citric acid in the same ethylene oxide condensate as was present in the slurry (the solution containing 20% citric acid), and the resulting granule cores were

further coated with dextrin and glucose (see col. 6, line 49 to col. 7, line 14). It is seen in these examples that the amount of the carrier (i.e., sodium hexametaphosphate in place of sodium tripolyphosphate) in the core is more than 20% of the total amount of the acid (i.e, sodium hexametaphosphate + citric acid) in the granule (as required in claims 22). Green, however, fails to specifically disclose the carrier to be sodium hexametaphosphate in amounts as those recited, the pH and pK_a values of the acidic buffer component.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected sodium hexametaphosphate as the carrier because this is one of the suitable selection of carriers taught by Green and to optimize its proportions within the amounts disclosed for sodium tripolyphosphates as they are used as carrier equivalents because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the prima facie case of obviousness. See *In re Boesch,* 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff* 919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller,* 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). With respect to the pH and pK_a values of the acidic buffer components, i.e., sodium hexametaphosphate in the core, and the citric acid in the preliminary coating, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect the pH and pK_a

values of the acidic buffer components to be within those recited because the same components have been utilized.

6. Claim 28 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Green as applied to the above claims, and further in view of Rahman et al. (US Patent No. 6,355,607), hereinafter "Rahman".

Green teaches the features as described above. Green, however, fails to disclose the acidic buffer component being Na_2H-citrate.

Rahman, in an analogous art, teaches acids having a builder property such as disodium hydrogen citrate (see col. 2, lines 14-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the builder carrier of Green Izawa with disodium hydrogen citrate because the substitution of one builder for another is within the level of ordinary skill in the art. In addition, the substitution of one builder for another is likely to be obvious when it does no more than yield predictable results.

7. Claims 18-24, 26, 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa et al. (US Patent No. 5,858,952), hereinafter "Izawa" in view of Bertacchi et al. (US Patent No. 6,242,407), hereinafter "Bertacchi".

Izawa teaches an enzyme-containing granulated product containing, in a uniformly dispersed state, an enzyme and one or more stabilizers selected from the group consisting of reducing agents and antioxidants; a method for the production of the

granulated product, as well as bleaching agents and detergent compositions containing the granulated product (see abstract). Examples of stabilizers include reducing agents, antioxidants, or mixtures thereof, and an example of an antioxidant is ascorbic acid (see col. 2, lines 43-48). The amount of enzymes contained in the granulated product is between 0.01 and 50% by weight (see col. 2, lines 55-62). The amount of stabilizers vary depending on the types of enzymes employed, preferably between 0.1 and 3,000% by weight, more preferably between 1 and 500% by weight, and particularly preferably between 10 and 300% by weight, calculated in relation to the amounts of enzyme protein (see col. 2, line 62 to col. 3, line 1). Powdery bulking agents may also be added if needed, and one example is sodium citrate (see col. 3, lines 42-52). The method for the manufacture of the granulated product includes spray-drying, freeze-drying, extruding, tumbling, fluidized-bed granulation, spray granulation and disintegration granulation (see col. 3, line 63 to col. 4, line 28). The enzyme-containing granulated product preferably has a coating thereon so as to obtain even further improved stability (see col. 4, lines 33-36). Materials used for coating the enzyme-containing granulated product are not particularly limited, and they may include water-soluble film-forming polymers like polyacrylate (see col. 4, lines 33-43). Coating materials are preferably used in a ratio by weight of 0.1 to 0.7 when the amount of the enzyme-containing granulated product is taken as 1 (see col. 4, lines 47-50). The amount of the enzyme-containing granulated product to be incorporated into a detergent composition is preferably between 0.001 and 70% by weight (see col. 5, lines 6-11). Izawa, however,

fails to specifically disclose a core comprising citric acid or adipic acid, the amount of stabilizer within those recited, and the pH and pK_a values as those recited.

Bertacchi, an analogous art, teaches the equivalency of ascorbic acid with citric acid or adipic acid as antioxidants (see col. 3, lines 45-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ascorbic acid antioxidant of Izawa with citric acid or adipic acid because the substitution of art recognized equivalents as shown by Bertacchi is within the level of ordinary skill in the art. In addition, the substitution of one antioxidant for another is likely to be obvious when it does no more than yield predictable results.

With respect to the amount of stabilizer in the core, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the portion of the prior art's range (i.e., between 0.1 and 3,000% by weight in relation to the enzyme) which is within the range of applicants' claims because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the prima facie case of obviousness. See *In re Boesch,* 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff* 919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller,* 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). In addition, a *prima facie* case of obviousness exists because the claimed ranges "overlap or lie

inside ranges disclosed by the prior art", see *In re Wertheim,* 541 F.2d 257,191 USPQ 90 (CCPA 1976; *In re Woodruff;* 919 F.2d 1575,16USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2131.03 and MPEP 2144.05I.

With respect to the pH and pK_a values of the citric acid or adipic acid, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect these components to possess a pH and pK_a values within those recited because similar components have been utilized.

8. Claims 27-28 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa in view of Bertacchi as applied to the above claims, and further in view of Rahman.

Izawa and Bertacchi teach the features as described above. Izawa and Bertacchi, however, fail to disclose NaH_2PO_4 or Na_2H-citrate.

Rahman, in an analogous art, teaches the equivalency of citric acid with disodium hydrogen citrate and sodium dihydrogen phosphate as acidification components (see col. 2, lines 14-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the citric acid of Izawa and Bertacchi with disodium hydrogen citrate or sodium dihydrogen phosphate because the substitution of art recognized equivalents as shown by Rahman is within the level of ordinary skill in the art.

Response to Arguments

9. Applicants' arguments filed on August 28, 2009 have been fully considered but they are not persuasive.

With respect to the 112, first paragraph rejection, Applicants argue that the specification on page 5 provides support for the limitations recited in instant claims 36-39, and argues that since Applicant included multiple designations e.g., more than 50%, more than 60%, more than 70%, it is clear that Applicant was in possession of the percentages between the numbers, including at least 51%, 52%, 54% or 56%.

The Examiner respectfully disagrees with the above arguments because, as stated in MPEP 2163.05: *The failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breath of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. 112, para.1, …, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure (underlining supplied).* See also MPEP 2163.05 III.

With respect to the rejection based upon Green, Applicants argue that one of ordinary skill in the art would not envision the success of using the acidic buffer component over the alkaline constituents and there is no disclosure that the acidic buffer component having a pH of 1 to below 7 when measured as a 10% aqueous solution and a pK_a in the range of 4 to 9 would increase the storage stability. Applicants

also pointed out Examples 1-4 in the specification and stated that unexpected advantages in using acidic buffer component was shown in combination with a detergent enzyme having an alkaline pH activity optimum.

The Examiner respectfully disagrees with the above arguments because in col. 2, lines 57-58, it is clear that Green teaches, as one carrier, among a few, sodium hexametaphosphate which read on the acidic buffer component required in the present claims. The carrier (i.e., granular sodium tripolyphosphate) in the enzyme granules of Green is present in an amount of 81% as shown in Example No. 1 in col. 5, lines 60-66. Other exemplified amounts of the carrier include 77.4%, 75.5%, 68% and 67%, respectively (see Examples 4-7 under col. 6). Inasmuch as sodium hexametaphosphate is taught as one of the carriers, this compound can also be used in the recited amounts as the sodium tripolyphosphate, and said amounts overlap those recited. Even though Green is silent as to the pH and pK_a of sodium hexametaphosphate, "products of identical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (fed. Cir. 1990). See MPEP 2112.01 II. The Examiner has carefully considered Examples 1-4 in the specification, however, the showing is not commensurate in scope with the present claims. Example 1 is limited to NaH_2PO_4, KH_2PO_4 and Na_2H-citrate whereas the present independent claims 18 and 32 recite a selection of acidic buffer components other than the three compounds discussed above. As to the showing, it is expected that an

increase in buffer component increases the stability of the enzyme. Example 2 shows coating the enzyme, however, the present independent claims require a core comprising a uniform mixture of a detergent enzyme with the acidic buffer component, not just coating it. Example 3 is limited to only NaH_2PO_4 as the acidic buffer component. In addition, said NaH_2PO_4 in the core is only 40% whereas the independent claims require more than 50% of the acidic buffer component in the core. In addition, the showing contains additional NaH_2PO_4 in the coating, which additional coating is not required in the independent claims. Example 4 shows coating the enzyme with polyacrylic acid, which showing is not commensurate in scope with the present independent claims.

With respect to the rejection of claim 28 based upon Green in view of Rahman, Applicant argues that claim 28 depends upon claim 18 and is thus not obvious for the same reasons claim 18 is not obvious.

The response to Green above applies here as well.

With respect to the rejection based upon Izawa in view of Bertacchi, Applicants argue that Izawa fails to teach at least 50% of the core is one or more of the specific acidic buffer components and that Bertacchi fails to cure the deficiencies of Izawa and argues that one of ordinary skill in the art would not envision the success of using constituents in a liquid bleaching formula of Bertacchi in an enzyme granule.

The Examiner respectfully disagrees with the above arguments because, as stated in the previous office action, and which is repeated in paragraph 7, Bertacchi is relied upon in his teaching of the equivalency of ascorbic acid with citric acid or adipic

acid as antioxidants (see col. 3, lines 45-47). Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ascorbic acid antioxidant of Izawa with citric acid or adipic acid because the substitution of art recognized equivalents as shown by Bertacchi is within the level of ordinary skill in the art. In addition, the substitution of one antioxidant for another is likely to be obvious when it does no more than yield predictable results. With respect to the amount of the citric acid or adipic acid, as antioxidants, Isawa teaches that the amount of stabilizers or antioxidants vary depending on the types of enzymes employed, preferably between 0.1 and 3,000% by weight, more preferably between 1 and 500% by weight, and particularly preferably between 10 and 300% by weight, calculated in relation to the amounts of enzyme protein (see col. 2, line 62 to col. 3, line 1).

With respect to the rejection of claims 27-28 based upon Izawa in view of Bertacchi and further in view of Rahman, Applicant argues that claims 27-28 depend upon claim 18 and is thus not obvious for the same reasons claim 18 is not obvious.

The response to Izawa and Bertacchi above applies here as well.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is 571-272-1313. The examiner can normally be reached on Mondays-Fridays 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorna M Douyon/
Primary Examiner, Art Unit 1796